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BY THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of) Group Art Unit 3775
Jean-François BIEGUN and) Nicholas W. Woodall, Examiner
Pascal MARCEAUX)
Serial No.: 10/534,567)
Filed: May 12, 2005)
For: ACCESSORIES FOR)
REMOVING BONE MATERIAL)
AND METHOD FOR MAKING)
SAME)

CERTIFICATE OF MAILING

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Patricia Oakes

Patricia Oakes, Secretary to Edward G. Greive

APPEAL BRIEF PURSUANT TO 37 CFR 41.37

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal to the Board of Patent Appeals from the rejections in the Final Office Action mailed June 9, 2010. The Notice of Appeal was received by the Patent Office on September 10, 2010. The present appeal is of claims 12, 13, 15-21, and 25. The fee of \$270.00 is submitted herewith.

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Real Party in Interest

The real parties in interest are the inventors, Jean François Biegun and Pascal Marceaux.

Related Appeals and Interferences

Not applicable.

Status of Claims

Claims 1-11, 14, and 22-24 have been cancelled.

Claims 12, 13, 15-21, and 25 have been rejected, and all are appealed.

Status of Amendments

No amendments were made after final rejection.

Summary of Claimed Subject Matter

Two independent claims are on appeal. Claim 21 recites a rasp for removing a part of a bone from the bone. Claim 20 recites a method for manufacturing a rasp for removing a part of a bone from the bone.

Claim 21 claims a rasp for removing a part of a bone from the bone. The rasp includes protrusions made of a plastic material which are to come into contact with the part of the bone and to rasp it from the bone. (part 3 of Fig. 1 and part 3 and inserts 4 of Fig. 5; and, page 4, line 20 – page 5, line 4). The plastic material is hard enough for the removal of hip bone. (page 2, lines 9-11). The rasp wears out after a single use. (page 2, lines 17 – 21). When the rasp is put into an autoclave at at least 137°C, the rasp deteriorates itself and cannot be further used. (page 2, lines 22 – 28; and page 3, lines 16 – 18).

Claim 20 claims a method for manufacturing a rasp for removing a part of a bone from the bone. The method includes the step of providing a body having the shape of a rasp which has protrusions made of a plastic material which are to come into contact with the part of the bone and to rasp it from the bone when the rasp is used to remove the part of the bone. (page 4, line 20 – page 5, line 4). The plastic material is exposed to β or γ rays. (page 2, line 29). After this exposition, the plastic material is hard enough to remove the part of the bone from the bone. (page 2, lines 9 – 11). The rasp wears out after a single use. (page 2, lines 17 – 21). When the rasp is put into an autoclave at at least 137°C, the rasp deteriorates itself and cannot be further used. (page 2, lines 22 – 28; and page 3, lines 16 – 18).

Grounds of Rejection to Be Reviewed on Appeal

- I. Whether claims 12, 13 and 20 fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph.
- II. Whether claim 21 is anticipated by Geisser (U.S. Patent No. 5,454,815)
- III. Whether claim 25 is obvious in view of Geisser and Morgan (U.S. Patent No. 5,910,106)
- IV. Whether claim 20 is obvious in view of Geisser and Morgan.

Argument

I. **Claims 12, 13 and 20 Are Supported by the Originally Filed Disclosure**

Claims 12, 13 and 20 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Particularly, the Examiner asserts that the “claim(s) contains subject matter which was not described in the specification.... Claim 20 appears to imply a limitation directed to the exposing of the plastic material to radiation hardens the material.... A limitation directed to the exposure of a plastic material to radiation to harden the plastic material is not supported by the disclosure as originally filed.”

This position is in error because the Examiner seems to be finding causation in the claim, but it is not so limited – the claim simply recites a physical property condition for the plastic material that must be satisfied after the step of exposing the plastic material to β or γ rays (“exposing said plastic material to β or γ rays, so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone...”). These recitations are clearly supported by the originally filed disclosure, and no new matter has been added to the claims.

The originally filed disclosure teaches rasps, cutting units, and ancillaries made of **plastic that is hard enough to rasp bone**:

However, as the plastic used is hard enough, it will be suitable for removing bone and withstanding the pressures associated with the action of a blade on the bone. In addition, by producing the ancillary in plastic, there are greater capacities for manufacturing a single-use, so-called “disposable” ancillary.

As a result of an improvement to the invention, the **hardness of the plastic is chosen** close to the bone hardness, for example between 5 and 30% higher.

By producing the **rasp or cutting unit in this material** therefore, we make sure that the ancillary can only be used for a single operation since the material rapidly wears out during the operation...

page 2, lines 9-19 (emphasis added).

The originally filed disclosure also teaches that the plastic is exposed to β or γ rays (page 2, lines 22-29) as part of a sterilization step. Thus, the originally filed disclosure teaches that the plastic is exposed to β or γ rays, and that after this exposure, a rasp constructed of the plastic is "hard enough...for removing bone."

The claims being fully supported by the originally filed disclosure, the Examiner's rejections under 35 U.S.C. § 112, first paragraph, should be reversed.

II. Claim 21 Is Not Anticipated: Each and Every Element Set Forth in the Claim Is Not Found in Geisser.

Claims 15, 16, and 21 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Geisser (U.S. Patent No. 5,454,815). Independent claim 21 defines, *inter alia*, a rasp for removing a part of a bone from the bone, comprising protrusions made of a plastic material which are to come into contact with the part of the bone and to rasp it from the bone, the plastic material being hard enough for the removal of hip bone. Geisser does not teach a rasp that is actually hard enough to remove bone.

The declaration of inventor Jean François Biegun¹ establishes that a rasp constructed according to the concepts of the Geisser invention (without exposure to β or γ rays) has a hardness value less than the hardness value of hip bone. Biegun's declaration further establishes:

1. That he has manufactured two bone rasps -- one according to the concepts of the present application with a pre-treatment of exposition to Beta or Gamma rays, and another according to the prior art without a pre-treatment of exposition to Beta or Gamma rays.
2. That the bone rasp prepared according to the concepts of the claims of the present application has a Shore D Hardness value of 85.3.
3. That the prior art bone rasp has a Shore D Hardness value of 83.3.

¹ Included in Evidence Appendix.

4. That the Shore D Hardness value of the cortical bone ranges between 85 and 95.
5. Since the prior art bone rasp (such as a rasp disclosed in Geisser) is not as hard as the bone to be rasped, it is therefore not able to rasp bone.

Thus, the rasp of Geisser is not hard enough to remove hip bone. As one having almost 20 years of experience in the art, Mr. Biegun also noted that prior art polycarbonate rasps, such as those taught in Geisser, have never been able to rasp bone because prior art rasps are not hard enough.

In further support of this contention, the Appellants note that a later-filed patent to Grünig (U.S. Patent No. 6,120,508)², criticizes the plastic rasps taught in Geisser as having problems when used on hard bone material and with longer application times:

Therefore, disposable rasps have already been proposed for only one-time use. EP-A-0 563,585 and EP-A-0 574,701 show disposable rasps made of plastic. In the production of such rasps from biocompatible plastic material, however, problems may arise with the rasp action, particularly in hard bone material and with longer application times.

(Grünig, col. 1, lines 30-37). The Board will quickly be able to verify that both Geisser and EP-A-0 563,585 claim priority to the same Swiss patent application, CH19920001043. Thus, the inventors of Grünig appreciated that the prior art rasps "proposed" by Geisser were ineffective. Instead of teaching an improved plastic rasp, those of skill in the art in 1999 reverted to using a rasp having metal teeth. (Grünig, col. 2, lines 30-31).

MPEP Section 716.07 instructs that "[w]here the affidavit or declaration presented asserts that the reference relied upon is inoperative, the claims represented by applicant must distinguish from the alleged inoperative reference disclosure." citing *In re Crosby*, 157 F.2d 198, 71 USPQ 73 (CCPA 1946). Claim

² The Grünig reference lists Albert Geisser (of Ennetburgen, Switzerland) as an inventor, the same being the first-named inventor of the "Geisser" reference cited against the claims. The face of both the Grünig and Geisser patents suggests that the patents were assigned to the same entity, either IMT Integral Medizintechnik AG or IMT Integral Medizintechnik Trading AG.

20 does distinguish the apparatus of Geisser, because the claim requires the rasp be hard enough to remove bone.

In view of Biegun's declaration that a prior art rasp made without a pre-treatment of exposition to β or γ rays is not hard enough to rasp bone, and Grünig's criticism of the technology disclosed in Geisser, the Board should find that the claims distinguish the teachings in Geisser and reverse the Examiner's rejection.

III. Claim 25 Is Not Obvious: No Motivation to Combine Morgan with Geisser.

Claim 25 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Geisser in view of Morgan (U.S. Patent No. 5,910,106). In particular, the Examiner stated that "Morgan teaches exposing a plastic medical instrument with gamma radiation in order to sterilize the device."

It is the position of the Appellants that since Geisser is insufficient to support the rejection of independent claim 21, and Morgan does not cure the deficiency, the combination of Geisser and Morgan does not disclose the claimed invention and the rejection should be reversed.

Specifically, because the stated object of Geisser is to "provide a rasp that avoids the cleaning and sterilizing steps and yet is always sterile and ready for operation," (Geisser, beginning at col. 1, line 42), one of skill in the art of bone rasps would have no reason to consider other references aimed at sterilizing a device. Moreover, since Geisser specifically teaches that its rasp "has therefore neither to be cleaned nor sterilized," (beginning at col. 1, line 62), one would not turn to the teachings in Morgan which relate to sterilizing a tool that has "neither to be cleaned nor sterilized."

The Federal Circuit has instructed that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed Cir. 2006). This proposition was cited with approval in *KSR v. Teleflex*, 127 S. Ct. 1727, 1741

(2007). There is no rational underpinning to the Examiner's suggestion to combine the teachings of Geisser and Morgan, and therefore the rejection should be reversed.

IV. Claim 20 Is Not Obvious: No Motivation to Combine Morgan with Geisser.

Claim 20 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Geisser in view of Morgan. This claim defines a method for manufacturing a rasp and recites, *inter alia*, the steps of providing a body comprising protrusions made of a plastic material and exposing the plastic material to β or γ rays, so that after this exposition, the plastic material is hard enough to remove the part of the bone from the bone. As argued above, Geisser does not teach a rasp that is actually hard enough to remove bone, and Morgan does not cure this deficiency. Accordingly, the rejection should be reversed.

Moreover, the Examiner acknowledges that "Geisser fails to disclose the method further comprising the step of exposing the device to gamma or beta radiation", and turns to Morgan for its teaching of "exposing a device to gamma radiation in order to sterilize the device." However, because Geisser provides "a rasp that avoids the cleaning and sterilizing steps" and "has therefore neither to be cleaned nor sterilized", one of skill in the art would not be motivated to sterilize a device that has "neither to be cleaned nor sterilized." Thus, there is no rational underpinning to the Examiner's conclusion of obviousness and the rejection should be reversed.

V. Conclusion

The 35 U.S.C. §§ 112, 102 and 103 rejections of the Examiner are not sound and should be reversed. The Appellants respectfully request such a finding from the Board.

Respectfully submitted,

Edward G. Greive
Edward G. Greive, Reg. No. 24,726
Renner, Kenner, Greive, Bobak, Taylor & Weber
First National Tower, Suite 400
106 S. Main Street
Akron, Ohio 44308-1412
Telephone: (330) 376-1242

Attorney for Appellants

November 9, 2010

Claims Appendix

- 1-11. (Canceled).
12. The method of claim 20, further comprising the step of embedding at least one insert of a material harder than bone in the plastic material.
13. The method of claim 12, wherein the at least one insert is fully embedded in the plastic material.
14. (Canceled).
15. The rasp as recited in claim 21, wherein said rasp also comprises at least one insert of a material which is harder than bone, said at least one insert being at least partly embedded in said plastic material.
16. The rasp as defined in claim 15, wherein said at least one insert is fully embedded in said plastic material.
17. The rasp as defined in claim 15, wherein said at least one insert is a metal.
18. The rasp as defined in claim 16, wherein said at least one insert is a metal.
19. The rasp as defined in claim 21, wherein said rasp comprises a part of a shape memory material harder than said plastic material.

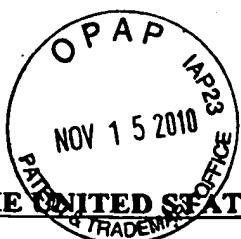
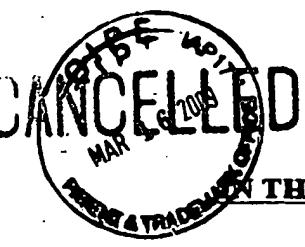
20. A method for manufacturing a rasp for removing a part of a bone from the bone, comprising the steps of:
providing a body having the shape of a rasp and comprising protrusions made of a plastic material which are to come into contact with the part of the bone and to rasp it from the bone when said rasp is used to remove the part of the bone; and
exposing said plastic material to β or γ rays, so that after this exposition, said plastic material is hard enough to remove the part of the bone from the bone when said rasp is used and wears out after a single use, and when said rasp is put into an autoclave at at least 137°C, said rasp deteriorates itself and cannot be used anymore.
 21. A rasp for removing a part of a bone from the bone, comprising protrusions made of a plastic material which are to come into contact with the part of the bone and to rasp it from the bone, said plastic material being hard enough for the removal of hip bone, and wherein said rasp wears out after a single use and when said rasp is put into an autoclave at at least 137°C, said rasp deteriorates itself and cannot be used anymore.
- 22 – 24. (Canceled).
25. The rasp as defined in claim 21, wherein said plastic material is exposed to β or γ rays.

Evidence Appendix

A Declaration of Jean François Biegun was entered with Amendment E, filed March 12, 2009, and is attached following this paper.

Related Proceedings Appendix

Not applicable.



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jean François Biegun

Serial N°.: 10/534,567

Filed: 11/14/2003

Title: Accessories for removing bone material and method for making same

Examiner:Nicholas Woodall

Attorney Docket N°.:CAC.P0046

DECLARATION OF Jean François BIEGUN

I, Jean François Biegun, hereby declare as follows:

I am the inventor in the above identified application, and I am currently the general manager of XNOV a French based company specialized in the manufacture of knee and hip prosthesis as well as of ancillaries and accessories related to such prosthesis, in particular ancillaries and accessories for removing the hip or knee bone in view of the installation of such prosthesis. I have been working in this field for almost 20 years and have been the designated inventor of many US granted patent in the field.

I have manufactured a femoral rasp in polycarbonate (Makrolon 2858 from Bayer) and I have had the Shore D Hardness of two samples (one without pre treatment and another one with a pre treatment consisting of exposition to Beta or Gamma rays in view of sterilization) and have found the following results:

For the first sample (no Beta or Gamma rays exposition) the medium value of the Shore D Hardness was found to be 83.3.

For the second sample (pre treated with Beta or Gamma rays exposition) the medium value of the Shore D Hardness was found to be 85.3.

It should be emphasized that the value of the D shore Hardness of the cortical bone ranges between 85 and 95, depending on which part of the bone the shore is being computed and that in the case of the cortical hip or femoral bone which is being rasped in the field of hip or bone prosthesis, it is the less hard part of the bone which is usually being rasped, ie the part of the bone with a D shore Hardness around 85.

It should then be pointed out that with the Beta or Gamma rays exposition pre treatment of the polycarbonate based rasp, it is obtained a value of the hardness which is higher than the one of the bone to be rasped, while without such pretreatment, the hardness stays beyond the hardness of the bone. This explains why prior art polycarbonate based rasp such as described in US 5454815 has never been able to rasp bone, while our new pre treated rasp is indeed able to rasp bone.

I further declare that all statements made herein of my own knowledge are true and that all statements made herein on information are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Made in Belfort on March 4th, 2009



Jean François Biegun